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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,266	03/27/2002	Tadao Ohno	P21324	9535

7055 7590 04/03/2006

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EXAMINER	
YU, MISOOK	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 04/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/890,266	OHNO ET AL.	
	Examiner	Art Unit	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 3-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-7,9,11-16,18 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/24/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 24 January 2006 has been entered.

Claims 1 and 3-19 are pending and examined on merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102, Withdrawn

The rejection of claims under 35 U.S.C. 102(b) as being anticipated by WO 98/16238 (Hiserodt, 23 April 1998, IDS fled on 30 July 2002) is withdrawn in view of the new rejection

Claim Rejections - 35 USC § 103, Withdrawn

The rejection of claims 1, 4, 5, 8-19 under 35 U.S.C. 103(a) as being unpatentable over WO 98/16238 of record (Hiserodt, 23 April 1998, IDS fled on 30 July 2002, cit) in view of US Pat. 5, 861,159 of record (Pardoll, 19 January 1999) is withdrawn in view of the new rejection below.

The Following Are New Grounds of Rejections

Claim Rejections - 35 USC § 102

Claims 1, 3-7, 9, 11-16, 18, and 19 are newly rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. 5, 861,159 (19 January 1999).

This is reinstatement of previously withdrawn rejection.

Claim 1, and its dependent claims are drawn to a composition comprising two main components of (1) "a microparticle" comprising a fragment of solidified tumor tissues or cells, wherein the size of the fragment to allow phagocytosis, and (2) at least one isolated cytokine or cytokine-inducing agent, wherein the dependent claim 3 further limits that the composition of the base claim further comprises an adjuvant, wherein claim 4, 5, 12-16 further limit the base claim that the tumor vaccine comprises granulocyte-macrophage-colony stimulating factor (GM-CSF), interleukin- 2, or a cytokine-controlled release preparation, and claim 19 further limits that the fragment of the base claim is a tumor antigen bound to a particle. Claim 6 is drawn to vaccine composition comprising a microparticle" comprising a fragment of solidified tumor tissues or cells, wherein the size of the fragment to allow phagocytosis, and the vaccine further comprises an adjuvant in the dependent claim 7.

The '159 patent at column 9, lines 5-28 discloses:

> It is also possible to incorporate purified antigens, such as those associated with a particular pathogen or tumor, either as whole molecules or in the form of immunogenic peptides into these polymers. Such an approach is enhanced when the specific identity of the relevant antigen(s) is known. For example, papilloma virus or immunogenic antigens from this virus would be useful to treat papilloma-associated cervical cancer. The virus, viral antigen(s), either alone or in combination, would be inserted into a delivery vehicle as described herein, either alone or in combination with a cytokine.

> The therapeutic mixture of vehicle/antigen used according to the method of the invention may also be administered to the subject in a delivery system, such as synthetic or natural polymers, in the form of macromolecular complexes, nanocapsules, microspheres, or beads, and lipid-based systems including oil-in-water emulsions, micelles, mixed micelles, synthetic membrane vesicles, and resealed erythrocytes. These systems are known collectively as dispersion systems. Typically, the particles comprising the system are about 20 nm-50 μM in diameter. The size of the particles allows them to be suspended in a pharmaceutical buffer and introduced to the subject using a syringe.

The '159 patent teaches a controlled release vehicle containing GM-CSF or interferon (note for example, claim 10), and adjuvant at column 3 line 11, where the GM-CSF containing particle acts as adjuvant.

The '159 patent does not teach that the particle "20 nm-50 μm in diameter" with a tumor antigen incorporated meets the limitation is a "a size so as to allow phagocytosis" However, Kwiatkowska et al., (1999, BioEssays, vol. 21, pages 422-431) at page 422, left column, line 4 teach "during phagocytosis large particles, at least 0.5 μm in diameter, are internalized". Thus, the tumor vaccine comprising the particle size of 20 nm-50 μM in diameter of the '159 paten inherently possess the fragment being of a size so as to allow phagocytosis of the fragment.

Conclusion

Claims 8, 10, and 17 are objected because they depend on the rejected base claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D.
Primary Examiner
Art Unit 1642